SEP - 5 2003 K 032507

510(k) Summary

Applicant/Sponsor: Biomet Orthopedics, Inc.
P.O. Box 587
Warsaw, Indiana 46581-0587

Contact Person: Patricia Sandborn Beres
Senior Regulatory Specialist
Telephone: (219) 267-6639
Fax: (219) 372-1683

Proprietary Name: Interlok® Bio-Modular® Shoulder Humeral Stems

Common Name: Shoulder Humeral Stem

Classification Name:

1) Prosthesis, Shoulder, non-constrained, Cemented (21 CFR Section 888.3650)
2) Prosthesis, Shoulder, Semi-constrained, Metal/Polymer, Cemented (21 CFR Section 888.3660)
3) Prosthesis, Shoulder, Hemi-, Humeral, Metallic, Cemented or Uncemented (21 CFR Section 888.3690)

Legally Marketed Devices To Which Substantial Equivalence Is Claimed: Devices are a modification of The Bio-Modular® Shoulder System cleared in 510(k) K992119.

Device Description:

- Manufactured from Ti-6Al-4V
- Bi-planer tapered stem
- 30 grit blasted Interlok® surface finish
- Sizes 6mm x 70mm and 7-15mm x115mm, in 2mm increments, with fin, collar and alignment hole
- Sizes 6-15mm x 70mm, modified devices with no collar, fin or alignment hole.

Intended Use:

1) Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis
2) Rheumatoid arthritis
3) Revision where other devices or treatments have failed
4) Correction of functional deformity
5) Fractures of the proximal humerus, where other methods of treatment are deemed inadequate
6) Difficult clinical management problems, including cuff arthropathy, where other methods of treatment may not be suitable or may be inadequate

Non-coated (Interlok®) devices are indicated for cemented application only.

Summary of Technologies: The design, materials and processing of the device are similar to the predicate device.

Clinical/Non-Clinical Testing: None provided

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 5 2003

Ms. Patricia Sandborn Beres
Senior Regulatory Specialist
Biomet, Inc.
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K032507
Trade/Device Name: Interlok® Bio-Modular® Humeral Stems
Regulation Number: 21 CFR 888.3650, 888.3660, 888.3690
Regulation Name: Shoulder joint metal/polymer non-constrained cemented prosthesis, Shoulder joint metal/polymer semi-constrained cemented prosthesis, Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis
Regulatory Class: II
Product Code: KWT, KWS, HSD
Dated: August 13, 2003
Received: August 14, 2003

Dear Ms. Beres:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K032507

Device Name: Interlok® Bio-Modular Shoulder Humeral Stems

Indications For Use:

1) Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis
2) Rheumatoid arthritis
3) Revision where other devices or treatments have failed
4) Correction of functional deformity
5) Fractures of the proximal humerus, where other methods of treatment are deemed inadequate
6) Difficult clinical management problems, including cuff arthropathy, where other methods of treatment may not be suitable or may be inadequate

Non-coated (Interlok®) devices are indicated for cemented application only.

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K032507

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ___ OR Over-The-Counter Use
(Per 21 CFR 801.109)

(Optional Format 1-2-96)